DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 25, 2016

Mölnlycke Health Care US, LLC
Ms. Megan Bevill
Manager, Regulatory Affairs
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092

Re: K160379
Trade/Device Name: Exufiber Ag+ Antimicrobial Gelling Fibre Dressing
Regulatory Class: Unclassified
Dated: July 22, 2016
Received: July 25, 2016

Dear Ms. Bevill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160379

Device Name
Exufiber® Ag+ Antimicrobial Gelling Fibre Dressing

Indications for Use *(Describe)*
For over-the-counter use, Exufiber Ag+ may be used for:

- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

Under the supervision of a healthcare professional, Exufiber Ag+ is intended to be used on the following medium to high exuding wounds:

- Leg ulcers (venous stasis ulcers, arterial ulcers and ulcers of mixed etiology) and diabetic foot ulcers
- Pressure ulcers (partial and full thickness)
- Partial thickness burns
- Donor sites and other wounds that are prone to bleeding, such as debrided wounds
- Traumatic wounds
- Surgical wounds that heal by primary intention, such as dermatological and surgical incisions (e.g. orthopaedic and vascular), and surgical wounds left to heal by secondary intention, such as dehisced surgical incisions
- Oncology wounds with exudate, such as fungoides-cutaneous tumours, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma

Exufiber Ag+ may be used for management of wounds as an effective barrier to bacterial penetration of the dressing, as this may help to reduce the risk of infection.

Indicated wear time: up to seven (7) days.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared: August 23, 2016

Applicant:
Mölnlycke Health Care US, LLC
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092
Registration number: 3004763499
Owner/Operator Number: 8030877

Official Correspondent:
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Manager, Regulatory Affairs
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Trade/Proprietary Names: Exufiber Ag+ Antimicrobial Gelling Fibre Dressing

Regulation Name: Dressing, Wound, Drug

Device Class: Unclassified

Product Code: FRO

Predicate Device Name(s): Aquacel Ag Extra Hydrofiber Dressing with Silver and Strengthening Fiber (K121275)

Description of Device:
Exufiber Ag+ Antimicrobial Gelling Fibre Dressing is a highly absorbent and gel-forming wound dressing that is intended to be used on medium to high exuding wounds to absorb wound fluid, creating a soft gel and maintaining a moist wound healing environment. The dressing consists of a polyvinyl alcohol (PVA) pad or ribbon, coated on both sides with silver sulfate to act as a preservative in the dressing to inhibit or reduce microbial growth.

Intended Use/Indication for Use:
For over-the-counter use, Exufiber Ag+ may be used for:

- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

Under the supervision of a healthcare professional, Exufiber Ag+ is intended to be used on the following medium to high exuding wounds:

- Leg ulcers (venous stasis ulcers, arterial ulcers and ulcers of mixed etiology) and diabetic foot ulcers
- Pressure ulcers (partial and full thickness)
- Partial thickness burns
- Donor sites and other wounds that are prone to bleeding, such as debrided wounds
- Traumatic wounds

- Surgical wounds that heal by primary intention, such as dermatological and surgical incisions (e.g. orthopaedic and vascular), and surgical wounds left to heal by secondary intention, such as dehisced surgical incisions
- Oncology wounds with exudate, such as fungoides-cutaneous tumours, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma

Exufiber Ag+ may be used for management of wounds as an effective barrier to bacterial penetration of the dressing, as this may help to reduce the risk of infection.

Indicated wear time: up to seven (7) days.

Technological Characteristics:

Feature	Exufiber Ag+	Aquacel Ag Extra	Substantial Equivalence Comments
510(k) clearance	Subject of submission	K121275	NA
Rationale for inclusion	Subject of submission	Predicate device	NA
Manufacturer	Mölnlycke Health Care	ConvaTec Inc.	NA
Class name	Dressing, wound, drug	Dressing, wound, drug	Same classification as predicate
Class	Unclassified	Unclassified	Same classification as predicate
Product code	FRO	FRO	Same product code as predicate
Indication for use/Intended use	For over-the-counter use, Exufiber Ag+ may be used for: • Abrasions • Lacerations • Minor cuts • Minor scalds and burns Under the supervision of a healthcare professional, Exufiber Ag+ is intended to be used on the following medium to high exuding wounds: • Leg ulcers (venous stasis ulcers, arterial ulcers and ulcers of mixed etiology) and diabetic foot ulcers • Pressure ulcers (partial and full thickness) • Partial thickness burns • Donor sites and other wounds that are prone to bleeding, such as debrided wounds • Traumatic wounds • Surgical wounds that heal by primary intention, such as dermatological and surgical incisions (e.g. orthopaedic and vascular), and surgical wounds left to heal by secondary intention, such as dehisced surgical incisions • Oncology wounds with exudate, such as fungoides-cutaneous tumours, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma Exufiber Ag+ may be used for management of wounds as an effective barrier to bacterial penetration of the dressing, as this may help to reduce the risk of infection. Indicated wear time: up to seven (7) days.	For over-the-counter use, Aquacel Ag Extra may be used for: • Abrasions • Lacerations • Minor cuts • Minor scalds and burns Under the supervision of a healthcare professional, Aquacel Ag Extra may be used for the management of: • Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection • Partial thickness (2nd degree) burns • Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial and full thickness) • Surgical wounds left to heal by secondary intention such as dehisced surgical incisions • Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular) • Traumatic wounds • Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites • Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angioarcoma • Painful wounds • Infected wounds	The subject device is indicated for the same wound types as the predicate
Physical design	Nonwoven pad or ribbon	Nonwoven pad or ribbon	Same as predicate

Dressing properties	Highly absorbent, cohesive, gel forming	Highly absorbent, cohesive, gel forming	Same as predicate
Dressing material	Polyvinyl alcohol (PVA) fibres	Carboxymethylcellulose (CMC) fibres	The subject and predicate devices are both manufactured from highly absorbent base materials. Exufiber Ag+ has been shown to be suitable for its intended use through biocompatibility and bench testing. PVA has been cleared for use in wound care applications under K122634 (Iodofoam Iodophor Foam Dressing), and others.
Antimicrobial agent and content	Silver, in the form of silver sulfate 0.2 mg/cm^2, as silver	Ionic silver 0.18 mg/cm^2	The subject and predicate devices utilize similar antimicrobial agents but in different chemical forms. The silver sulfate used in the subject device is the same silver sulfate that is used in other Mölnycke silver dressings, including Mepilex Transfer Ag (K123892) and Mepitel Ag (K130040).
Single use or Reusable	Single Use	Single Use	Same as predicate
Sterility	Sterile (EtO)	Sterile (gamma)	The subject and predicate devices are both provided sterile and are sterilized by traditional methods. Mölnlcyke's Mepilex Transfer Ag (K123892) and Mepitel Ag (K130040) dressings are sterilized using the same EtO process as the subject device.

Performance Data:
In vitro and in vivo methods have been used to demonstrate the safety and effectiveness of the Exufiber Ag+ Antimicrobial Gelling Fibre Dressing with regards to the following parameters:

- Cytotoxicity
- Irritation
- Sensitization
- Wound healing model
- Antimicrobial efficacy against 11 strains
- Silver release kinetics
- Minimum effective concentration

Clinical Data:
No clinical data was required to support substantial equivalence.

Conclusion:
Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics as well as performance testing. Exufiber Ag+ is at least as safe and effective, and performs at least as well as the predicate device, Aquacel Ag Extra.